MAY 0 9 2002

510(k) Summary
(as required by 807.92(c))

Submitter of 510(k): Diatek, Inc.
101 N. Chestnut Street, Suite 300
Winston-Salem, NC 27101

Phone: 336-725-9711
Fax: 336-725-0035

Contact Person: Todd Cassidy

Date of Summary: January 29, 2002

Trade Name: Diatek Connector Assembly Replacement Kit

Classification Name: Catheter, Hemodialysis, Implanted

Predicate Device: Diatek Cannon-Cath

Intended Use:

The Diatek Connector Assembly Replacement Kit is to be used for replacing the original connector assembly on a Diatek Cannon-Cath Dialysis Catheter if the connector assembly becomes damaged or dysfunctional. This prevents the patient from requiring additional surgery for catheter removal and replacement.

The Connector Assembly Replacement Kit is intended for use in any patient who has a previously implanted Diatek Cannon-Cath implanted.

Device Description

The Diatek Connector Assembly Replacement Kit consists of a Cannon-Cath connector assembly and components needed to remove the previously implanted connector assembly and attach the new connector assembly to the previously implanted dialysis catheter.

Testing

The Diatek Connector Assembly Replacement Kit components by virtue of being identical to the components in the Diatek Cannon-Cath product have been tested by both internal and outside laboratories for a range of criteria and found acceptable as submitted in 510(k) 010399 for the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 9 2002

Mr. K. Todd Cassidy
Executive Vice-President
Diatek®, Inc.
101 North Chestnut St., Suite 300
WINSTON-SALEM NC 27101

Re: K020430
Trade/Device Name: Diatek® Connector Assembly Replacement Kit
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: 78 NFK
Dated: February 1, 2002
Received: February 8, 2002

Dear Mr. Cassidy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K020430

Device Name: Diatek Connector Assembly Replacement Kit (CARK)

Indications for Use:

The Diatek Connector Assembly Replacement Kit is to be used for replacing the original connector assembly on a Diatek Cannon-Cath Dialysis Catheter if the connector assembly becomes damaged or dysfunctional. This prevents the patient from requiring additional surgery for catheter removal and replacement.

The Connector Assembly Replacement Kit is intended for use in any patient who has a previously implanted Diatek Cannon-Cath Dialysis Catheter implanted.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

Nancy C Brogdon (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020430